510(k) Summary	
510(k) Number	To be assigned
Submitter Information:	
Date Prepared:	May 04, 2012
Submitter Name & Address:	Irvine Biomedical; Inc. a St. Jude Medical Company 2375 Morse Avenue Irvine, CA 92614
Contact Person:	Loucinda Bjorklund Sr. Regulatory Affairs Specialist Phone (651) 756-3230 Fax (952) 930-9481 LBjorklund@sjm.com
Device Information:	
Trade Name:	ViewFlex™ Xtra ICE Catheter
Common Name:	ICE Catheter
Class	II
Classification Name:	892.1550, System, Imaging, Pulsed Doppler Ultrasonic; ITX 892.1570, Transducer, Ultrasonic; 892.1560, System, Imaging, Pulsed Echo, Ultrasonic 892.1200, Diagnostic Intravascular Catheter
Predicate Device:	ViewFlex Plus Catheter (K101239)
Device Description:	The ViewFlex Xtra ICE Catheter is inserted into the heart via intravascular access. The ViewFlex Xtra is a sterile, single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. The ViewFlex catheter shaft is a 9 French catheter constructed with radiopaque tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement. The ViewFlex Xtra is compatible with ViewMate II and ViewMate Z ultrasound consoles.
Intended Use: (Indications for Use)	The ViewFlex Xtra ICE Catheter, part of the ViewMate System, is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.
Comparison to Predicate Devices	The ViewFlex™ Xtra ICE Catheter has the same intended use and fundamental scientific technology as the predicate device. The technological characteristics of the ViewFlex™ Xtra ICE Catheter are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Through biocompatibility and bench performance testing it was demonstrated that the design modifications do not adversely affect the safety and effectiveness.
Summary on Non-Clinical Testing	The results of bench testing demonstrated that the device meets the established performance specifications. The results of biocompatibility testing demonstrated that the modified design meets specifications in accordance with ISO 10993-1.
Statement of Equivalence	The ViewFlex Xtra ICE Catheter has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and predicate device has been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 7 2012

Irvine Biomedical, Inc.
St. Jude Medical Company
c/o Mrs. Loucinda Bjorklund
Sr. Regulatory Affairs Specialist
2375 Morse Avenue
Irvine, CA 92614

Re: K121381
Trade/Device Name: ViewFlex™ Xtra ICE Catheter
Regulatory Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II (two)
Product Code: IYO
Dated: May 4, 2012
Received: May 8, 2012

Dear Mrs. Bjorklund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____
Device Name: ViewFlex™ Xtra ICE Catheter

Indications for Use:

The ViewFlex™ Xtra ICE Catheter, part of the ViewMate™ System, is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121381